Vaccine Identification Standards Initiative (VISI)

Minutes of Conference Call
March 14, 2000
10:00 AM - 11:30 AM EST

CALL PARTICIPANTS

Bruce Weniger (moderator)	National Immunization Program/CDC
Bob Chen	National Immunization Program/CDC
Walt Orenstein	National Immunization Program/CDC
Bindi Patel	National Immunization Program/CDC
Susan Abernathy	National Immunization Program/CDC
Julie Gamez	National Immunization Program/CDC
Dinny Smith	Pharmacy Division/Texas Department of Health
Gene Trautman	Pharmacy Division/Texas Department of Health
Gina Butler-Galliera	SmithKline Beecham Pharmaceuticals
Katie Maher	Merck Vaccine Division
Cindy Dickson	Merck Vaccine Division
Cliff Harze	Merck Vaccine Division
Anne Marie Seppler	Wyeth-Ayerst Laboratories
Yvonne McHugh	Chiron
Ron Filipski	Pasteur Merieux Connaught
Fred Varrichio	Center for Biologics Evaluation and Research/FDA
Phil Perucci	Center for Biologics Evaluation and Research/FDA
Karen Chaitkin	Center for Biologics Evaluation and Research/FDA
Joanne Kim	American Academy of Pediatrics
John Roberts	Uniform Code Council (UCC) Inc.
Frank Sharkey	Uniform Code Council (UCC) Inc.
Steve Sepe	National Vaccine Program Office

SUMMARY

Introductions

Dr. Bruce Weniger welcomed all VISI participants and participants identified themselves and their institutions in turn.

Discussion on Specific VISI components

Before the conference call, VISI participants had been urged to review the draft prototypes posted on the VISI web site and related information. These were discussed, as follows.

1. Formal Narrative Text for VISI Promulgation

- Dr. Weniger stated that a specifications document, the overarching narrative text containing the background, rationale, methodology, principles, and detail of all VISI components, has not yet been drafted. However, he envisions a 5-10 page document to be distributed as an MMWR article or journal publication. He asked VISI members for suggestions in shepherding such a document through the public comment and final publication stages.

- Mr. John Roberts suggested that the best mode of communication would be to place the document on the Internet. He added that the UCC used the same mechanism to distribute its specifications and this route has been very successful. In terms of nomenclature, he suggested that what VISI intends to produce will be "standards", per se, but "Application Guidelines", as UCC applies the term.

- Dr. Frederick Varrichio suggested that we also announce or list the document in the Code of Federal Regulations.

- With the President's recent initiative to reduce medication errors, Dr. Chen stated that we want to be aware of other groups that have the same goal as VISI. Mr. Varrichio named organizations such as the "US Pharmacopeia" and "Institute for Safe Medication Practices" as examples of such groups. Ms. Bindi Patel will follow-up to make contact with them to learn of any related activities or guidance and to invite them to participate and contribute to VISI.

- Mr. Roberts stated that the UCC works internationally and that VISI's "application guidelines" move in this direction. Dr. Weniger agreed that we should strive for universality, especially in deriving abbreviations that may end up serving a variety of uses and needs besides vaccine labeling.

2. National Drug Code (NDC) Vaccine Database

- Dr. Weniger explained that VISI proposes using the NDC within vaccine label barcoding to uniquely identify vaccines. The NDC database will be a service for software developers writing "lookup tables" to identify a vaccine from its NDC number, and vice versa: to be able to find all the current and recent NDCs assigned to specific vaccine types, brands, manufacturers, etc..

- Ms. Patel stated that the information in the database was supplied by vaccine manufacturer liaisons to the VISI, as well as from package inserts. She further explained some glitches in the database which include layout problems when converting to html and browser-dependent

formatting changes.

- Ms. Gina Butler-Galliera asked whom manufacturers should contact to add new NDCs to the database when new vaccines and packaging are introduced to the market. Dr. Weniger stated that for the time being the point of contact would be Ms. Patel in CDC/NIP's Vaccine Safety and Development Branch (VSDB), and he encouraged all vaccine manufacturers to send corrections to the database to her.

- Dr. Weniger said it remained unsettled which agency (CDC?, FDA?) or unit within the agency assume long-term responsibility of maintaining the database.

- Dr. Chen observed that there is no participation in VISI by the medical software industry, and he suggested that immunization registry movement conferences would be a good venue to alert software vendors about VISI.

3. Vaccine Facts Information Sidebar

- Dr. Weniger explained the purpose of the "Vaccine Facts" sidebar, which would be analogous to the "Nutrition Facts" sidebar mandated by the FDA for all retail food packages in the US.

- Ms. Patel raised the issue of including antigen quantity information in the "Volume" field of the panel. Some VISI members suggested that it may be unnecessary to include information irrelevant to nurses or providers of the vaccines. Ms. Patel agreed and she will develop a series of prototypes illustrating the alternatives: one set with antigen quantity information and another without. They will be posted on the VISI web site for working group comment.

- Another issue raised by Ms. Patel was regarding the "Preservative" field. This field has been changed to "Additives" but there still remains the question of what types of additives be included, such as trace components of thimerosal, allergens (egg proteins), formaldehyde added during manufacturing and a proper label for this field.

- Dr. Varrichio suggested we develop two prototypes, one with all ingredients and another prototype listing possible ingredients. Another suggestion was to separate the "Additives" field into two categories, such as "trace components" and "adjuvants". Dr. Weniger agreed that we must continue to come up with better naming and labeling of this field.

- Ms. Gina Butler-Galliera pointed out that the location of the "Lot Number" and "Expiration Date" on the sidebar may not be compatible with on-line printing of cartons by some manufacturers. Mr. Ron Filipski and Ms. Cindy Dickson agreed and the suggestion was made to leave out the blank space reserved within Vaccine Facts for online printing of lot number and expiration date, which can be elsewhere on the secondary (cardboard box) packaging.

- Ms. Dickson asked how this information will fit onto small packages. Dr. Weniger stated that the information is already on the packages, and our goal is to rearrange it by standardizing its layout so medical staff can find it quickly and easily. He further stated that we leave it to the vaccine manufacturing industry to figure out how to label smaller cartons. It would seem

possible for the Vaccine Facts sidebar to wrap over one or two edges and appear on two or three adjacent faces of the vaccine box.

4. Bar coding of Secondary Packaging

- Dr. Weniger said VISI proposes that all secondary vaccine packaging (cardboard box) include a full-size barcode according to UCC-EAN 128 standards.

- Mr. Filipski pointed out that the full size barcode is three inches in length and will not fit on the vaccine cartons.

- Mr. Roberts assured the group that the information can be placed on the outside packaging by truncating the linear barcode or use composite symbology. He invited all vaccine manufacturers to send sample cartons to the UCC and his team can develop sample labels. VISI representatives from the vaccine manufacturing industry agreed to send their packages to the UCC.

- Dr. Weniger suggested a VISI subcommittee be formed of vaccine manufacturers and the UCC, with leadership from Mr. Frank Sharkey as Chair. Mr. Roberts invited the vaccine manufacturers to UCC in Lawrenceville (near Princeton), NJ to review sample labels and settle on an application guidelines within 60 days and report to the entire VISI group. Arrangements will be made by UCC to ensure compliance with antitrust laws. Ms. Patel will send all vaccine manufacturers the UCC contact information. [NOTE: After the call, a date of 27 April was set for this meeting in NJ and contact information for UCC was distributed. Contact information: John J. Roberts, Uniform Code Council Inc., 1009 Lenox Drive, Suite 202, Lawrenceville, NJ 08648 USA Phone (609) 620-4563 Fax (609) 620-1200 Cell (937) 609-3739 Email: jroberts@uc-council.org]

5. Barcoded Peel-off Stickers on Vials

- Dr. Weniger indicated that the previous generation of VISI propotype barcoded peel-off stickers (and still visible on the website) were obsolete, as they were much too large to fit on monodose vials. A new set of prototypes would be needed, probably using a reduced space symbology to fit them into much smaller spaced. Examples include the RSS Limited Composite™ or an RSS-14 Stacked Composite™. He added that affixing the sticker onto the vial -- rather than onto the carton, as now done for Pasteur Merieux Connaught's TriHIBit™ vaccine -- was a better method of vaccine identification. Vials are often stored separately from the opened boxes in clinics, and erroneous linkage of some stickers with the correct vials might occur.

- Dr. Weniger encouraged VISI participants to view the Swedish barcode samples located on the VISI web site: **http://www.cdc.gov/nip/visi/Slide-Show/swedishsticker.htm.** As better scans are made of the samples, these will be posted to this address.

- Ms. Butler-Galliera asked what the minimum information needed to be placed on the primary

label. Dr. Weniger responded that each peel-off sticker contain: (1) the representation in arabic numerals of the number string represented in the barcode (as required by UCC-EAN standards, and usually placed immediately below the barcode), (2) the boldfaced standardized abbreviation for the vaccine type, (3) the standardized abbreviation for the vaccine manufacturer, (4) the commercial brand name of the vaccine, (5) the NDC number, (6) the lot number (or the "pick" number for vaccines combined by the vaccinator from separate lots of different vaccines), and (7) the expiration date.

, Mr. Roberts again encouraged vaccine manufacturers to send product samples to the UCC and his team will produce draft vaccine vial stickers with the reduced space symbology. The task of designing the layout and format, as well as the barcoding, for such peel-off stickers was tasked to the VISI “barcoding subcommittee” to be led by UCC.

6. Uniform Vaccine Administration Record (UVAR) Form

, Ms. Patel stated that the latest form with the recent changes to the UVAR has not yet been updated to the VISI web site. She suggested VISI members consider adding two values for the “route of administration” box on the form: “inhalation” and “transcutaneous”, to be ready for future routes of vaccine administration.

, Dr. Weniger explained that the UVAR form was designed to accept either peel-off stickers from the vaccine vial, as well as the handwritten entry of vaccine information by the provider.

, Dr. Weniger invited VISI members to comment on the UVAR form. Ms. Maher suggested that input from users of the form would be useful. Ms. Joann Kim offered to obtain feedback on the form from AAP. It was also suggested that input from the American Nursing Association (ANA) be obtained. This will be welcomed informally at this stage, or formally during the public comment period. Much publicity will be sought for same, and it is expected there will be many public comments to sort through.

7. Uniform Vaccine Abbreviations

, Dr. Weniger asked VISI members for comments on the standardized vaccine abbreviations. The latest draft of the vaccine abbreviations elimiminated the Health Level Seven (HL7) codes used by immunization registries for electronic data exchange, as the linkage with the abbreviations was felt to be confusing and of no interest to the great majority of vaccine providers.

, Ms. Maher suggested that we seek input from medical record keepers.

, Dr. Weniger further explained that the clarifying subscripts on vaccine abbreviations were primarily to serve the scientific community and that for most routine vaccinations, such subscripts would not be needed.

8. Uniform Manufacturer Abbreviations

- Dr. Weniger asked VISI members for comments on the standardized manufacturer abbreviations. He pointed out that this set of abbreviations were separate from the"MVX Codes" for electronic data interchange for immunization registries, although they were derived from them.

- Ms. Susan Abernathy explained that the MVX code set follows standard coding rules, in which the code never changes, only the descriptor. She cited an example such as the code "MIP" for Michigan Biologic Products Institute. Recently, the company changed its name to BioPort, but the code for this company will permanently remain "MIP". "Formerly Michigan Biologic Products Institute" was added to the descriptor.

- Dr. Chen suggested the need for updated translation table that allows us to know the manufacturer of the vaccine when the dose was given and what the company is currently.

- Ms. Dickson suggested using the first four digits of the NDC code as identifiers of vaccine manufacturers. Dr. Weniger explained that this would be confusing since some manufacturers have 5-digit digit identifiers, and that numerical abbreviations would not satisfy the criteria that such abbreviations provide intuitive hints for the vaccine they represent. Because the MVX codes use letters that look like abbreviations, he indicated the importance of clarifying the difference and avoiding confusion between abbreviations and codes.

Next Steps

- A subcommittee will meet to develop sample bar coding prototypes for secondary and primary packaging. It will be chaired by Frank Sharkey from the UCC. Vaccine manufacturers are invited to send the UCC sample products, contact information, and necessary information to be placed on the barcode. The subcommittee will report back within 60 days.

- Another conference call was set for Wednesday, May 24, at 11:00am. The following call information will be repeated and distributed via email closer to the event:

Call name:	VISI
Date:	Wednesday, 24 May 2000
Time:	11:00 - 12:00 am EST (8-9 am PST)
Phone no.:	[+1] 404-639-4100
Toll-free in US:	1-800-713-1971
Access Code:	446220
Problems:	Call 404-639-7550 for technical difficulties with the teleconference equipment, or for manual link into the call.

- In the next few weeks, CDC will post revised prototypes on the VISI web site and will notify VISI members of the appropriate Internet address.

, Related reading:

Feikema SM, et al. Extraimmunization among US children. JAMA. 2000 Mar 8;283(10):1311-7. http://jama.ama-assn.org/issues/v283n10/full/joc91043.html#a4

Davis RL. Vaccine extraimmunization--too much of a good thing? JAMA. 2000 Mar 8;283(10):1339-40. http://jama.ama-assn.org/issues/v283n10/pdf/jed00012.pdf

VISI Contact

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